

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/022330

International filing date: 13 July 2004 (13.07.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/488,492
Filing date: 17 July 2003 (17.07.2003)

Date of receipt at the International Bureau: 06 September 2004 (06.09.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

1217818

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

August 26, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK
OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE.

APPLICATION NUMBER: 60/488,492

FILING DATE: July 17, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/22330

Certified by



Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
and Acting Director of the U.S.
Patent and Trademark Office

07/17/03
1541 U.S. PTO

Please type a plus sign (+) inside this box →

PTO/SB/16 (5-03)

Approved for use through 4/30/2003. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

17613 U.S. PTO
60/488492

INVENTOR(S)

Given Name (first and middle [if any]) Arthur H.K.	Family Name or Surname Djang	Residence (City and either State or Foreign Country) Jamestown, New York
---	-------------------------------------	--

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)
Herbal extract composition and method of making the same

Direct all correspondence to:

CORRESPONDENCE ADDRESS

<input type="checkbox"/> Customer Number	→					<input type="checkbox"/> Place Customer Number Bar Code Label here	
OR							
Type Customer Number here							
<input type="checkbox"/> Firm or Individual Name	Arthur H.K. Djang, M.D.						
Address	111 West Second Street						
Address	Suite 4000						
City	Jamestown	State	New York	ZIP	14701		
Country		Telephone	716-664-7255	Fax	716-484-0169		

ENCLOSED APPLICATION PARTS (check all that apply)

<input checked="" type="checkbox"/> Specification	Number of Pages	19	<input type="checkbox"/> CD(s), Number	
<input type="checkbox"/> Drawing(s)	Number of Sheets		<input type="checkbox"/> Other (specify)	acknowledgment postcard, certificate of mailing
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76				

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)

<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.	FILING FEE AMOUNT (\$)
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees	
<input type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.	\$80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

<input checked="" type="checkbox"/> No.	
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____	

Respectfully submitted,

SIGNATURE 

TYPED or PRINTED NAME M. Bud Nelson

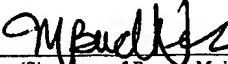
TELEPHONE 919-673-1092

Date 07/17/2003

REGISTRATION NO. 35,300
(if appropriate)
Docket Number: _____

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)			Docket No.
Applicant(s): DJang			
Serial No.	Filing Date 17 July 2003	Examiner	Group Art Unit
Invention: Herbal extract composition and method of making the same			
<p>I hereby certify that this <u>provisional application</u> <small>(Identify type of correspondence)</small></p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Director of the United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 on <u>17 July 2003</u> <small>(Date)</small></p>			
<p style="text-align: center;">M. Bud Nelson <small>(Typed or Printed Name of Person Mailing Correspondence)</small></p>  <small>(Signature of Person Mailing Correspondence)</small>			
<p style="text-align: center;">ER 306008589 <small>("Express Mail" Mailing Label Number)</small></p>			
<p>Note: Each paper must have its own certificate of mailing.</p>			

HERBAL EXTRACT COMPOSITION AND METHOD OF MAKING THE SAME

Field of the Invention

The present invention relates to an herbal extract-based composition comprised of an extract of Gynostemma pentaphyllum, an extract of Crataegus pinnatifidia, an extract of Camellia sinensis, an extract of mulberry (Morus species), and an extract of bitter melon (Momordica charantia). The present invention also provides a method of making the composition for therapeutic uses, and as a dietary supplement for promoting health.

Background of the Invention

Generally, herbal supplements are natural, safe when taken as recommended, and less expensive and sometimes more effective alternatives to drugs. These plant-based pharmaceuticals are used for medicinal purposes; and/or dietary supplements for disease prevention, for relief of ailments, and for health maintenance (collectively "health-promoting"). Gynostemma pentaphyllum, Crataegus pinnatifidia, Camellia sinensis, mulberry, and bitter melon each have been used individually for particular therapeutic applications.

1. Gynostemma pentaphyllum

Gynostemma pentaphyllum, also known as 5-leaf ginseng or jiaogulan or southern ginseng, is from the cucumber family and has traditionally been grown in a mountainous region in South Central China. This herb, a completely different plant than ginseng, is rich in special saponins termed "gypenosides" which are similar, and some identical, to the ginsenosides found in ginseng, but at a level several fold higher. These saponins have been shown to have antioxidant/cell protective effects. More particularly, the saponins protected cell membranes and cytosols, from oxidative injury, neutralize free radicals, helped preserve immune function during irradiation, lowered blood pressure, reduced vascular resistance, effects anti-platelet-aggregation, and reduced levels of serum

triglycerides and total cholesterol (Gormley et al., 1997, *Better Nutrition* 59:42).

2. Crataegus pinnatifidia

The leaves and berries of Crataegus pinnatifidia, also known as hawthorn, have been used traditionally for the treatment of heart conditions and for cardiovascular health. The hawthorn fruits (berries), known as "Shan-zha, have been used to improve digestion, and to alleviate various stomach ailments. Saponins, flavonoids (including hyperoside), and anthocyanins (including proanthocyanidins) extracted from hawthorn fruits have also shown cardiotonic (heart stimulating and regulating) activity including inhibition of arrhythmia, normalization of blood pressure, dilation of blood vessels and increase in coronary blood flow, reduction of serum triglyceride and cholesterol levels, reduction in symptoms of angina, and improvement of circulation (Foster, 1997, *Better Nutrition*, 59:56; Foster, 1989, *Bestways* 17:46; McCaleb, 1991, *Better Nutrition for Today's Living* 53:32).

3. Camellia sinensis

Dried leaves from the Camellia sinensis plant is processed into three types of tea: oolong tea, black tea, and green tea. In making green tea, the tea leaves are stabilized by moist or dry heat which destroys the enzyme polyphenoloxidase and thus, prevents oxidation of polyphenols. These polyphenols are the main biologically active ingredients in green tea. Catechins, a chemical group of polyphenols possessing antioxidant properties (protects cells from free radical-mediated damage), include epigallocatechin-3 gallate (ECGC), epigallocatechin, and epicatechin-3-gallate. Recently, ECGC has been shown to be an inhibitor of urokinase, an enzyme crucial for cancer growth (Jankun et al., 1997, *Nature* 387:561). The polyphenols in green tea, accounting for as much as 40% of tea's dry solids, have also been shown to reduce serum cholesterol and LDL (low density lipoprotein). Green tea polyphenols have been shown to prevent microbial (bacterial and viral) infections. For example, green tea

polyphenols damage bacterial membranes (Dolby, 1997, *Better Nutrition*, 59:22). Further, extracts of green tea have been shown to prevent cancers of the lung, breast, prostate, liver, skin, esophagus, and colon. Green tea is also high in cavity-fighting fluoride- the amount of tea used to prepare one cup has approximately 0.3 milligrams of fluoride.

4. Mulberry

Mulberry leaves and berries have been found to contain flavonoids, identified as morusin, kuwanon H, morusin-4'-glucoside, which have demonstrated anti-HIV activity (Luo et al., 1994, *Int. Conf. AIDS* 10:203 Abstract No. PB0240). Also another chemical isolated from mulberry, deoxynojirimycin ("DNJ"), inactivates HIV (Godlee, 1992, *British Med Journal* 305:1583). DNJ is a potent alpha glucosidase inhibitor which inhibits glucosidase I. DNJ is currently being evaluated as a supplement for use in preventing diabetes (Asano et al., 2001, *J. Agric. Food. Chem.* 49:4208-4213). Galactolipid compounds and a triterpene compound, contained in methanol extracts of mulberry leaves, have hypoglycemic activity when tested in streptozotocin-induced diabetic rats (Huh, 2000, *Korean J. Pharmacogn.* 31:95-100). Mulberry also contains resveratrol, a powerful antioxidant known to have anti-cancer effects (e.g., against skin cancer and leukemias), and to lower risk of heart attacks and heart disease.

5. Bitter melon

Bitter melon (Momordica charantia) is fruit indigenous to South America and Asia. Bitter melon appears to contain components having structural similarity to insulin, and has been used in alternative therapy for lowering glucose levels in individuals with diabetes mellitus (Basch et al., 2003, *Am. J. Health Syst. Pharm.* 60:356-9). Hypoglycemic effects have been noted with ingestion of powdered bitter melon fruit or bitter melon juice or extracts of bitter melon leaves (Grossman et al., 2001, *Drug Topics* 145:23). One of bitter melon's components, charantin, is composed of mixed steroids

that reportedly are more potent in action than the antidiabetic drug tolbutamid. Bitter melon is a component of the regular diet of the native population of Okinawa, a population having one of the highest life expectancies in the world.

A herbal extract-based composition comprising a novel combination of Gynostemma pentaphyllum, Crataegus pinnatifidia, Camellia sinensis has been described previously (U.S. Patent No. 5,910,308, to the present inventor and assignee); and Gynostemma pentaphyllum, Crataegus pinnatifidia, Camellia sinensis, mulberry, and bitter melon have been used individually for health promoting and therapeutic purposes. However, not described is the arrangement and herbal extract-based composition comprised of a combination of an extract of Gynostemma pentaphyllum, an extract of Crataegus pinnatifidia (hawthorn berries and/or leaves), an extract of Camellia sinensis (green tea), an extract of mulberry (Morus species; berries and/or leaves), and an extract of bitter melon (Momordica charantia; one or more of fruit, seed, or leaves) for health-promoting and/or therapeutic uses.

Summary of the Invention

This invention relates to a herbal extract-based composition that comprises a combination of components (in an amount expressed in percent by weight of the composition) wherein a first component comprises about 5 percent to about 20 percent by weight of Gynostemma pentaphyllum extract; a second component comprises about 20 percent to about 40 percent by weight of green tea extract; a third component comprises about 20 percent to about 40 percent by weight of hawthorn (berries and/or leaves) extract; a fourth component comprises about 10 percent to about 20 percent by weight of mulberry (berries and/or leaves) extract; and a fifth component comprises about 10 percent to about 20 percent by weight of bitter melon (fruit and/or seeds and/or leaves) extract. Preferably, the composition comprises about 10 percent by weight of Gynostemma pentaphyllum extract, about

20 percent by weight of green tea extract, about 30 percent by weight of hawthorn berries extract, about 20 percent by weight of mulberry (leaves and/or berries) extract, and about 20 percent by weight of bitter melon.

Another aspect of the present invention is a process for preparing the herbal extract-based composition. Essentially, this method comprises separately extracting each herbal component (hawthorn berries and/or leaves, green tea leaves, leaves of Gynostemma pentaphyllum, mulberry berries and/or leaves, and fruit and/or seeds and/or leaves of bitter melon); drying the extraction eluates to obtain the organic residues in forming a hawthorn extract powder, green tea extract powder, a Gynostemma pentaphyllum extract powder, a mulberry extract powder and a bitter melon extract powder; and combining the green tea extract powder, the Gynostemma pentaphyllum extract powder, the hawthorn extract powder, the mulberry extract powder, and the bitter melon extract powder in desired proportions to form the herbal extract-based composition. In one embodiment, this method comprises the steps of:

- (a) separately extracting a first batch of macerated (e.g., cut and/or torn) hawthorn (berries and/or leaves), macerated green tea leaves, macerated Gynostemma pentaphyllum leaves, macerated mulberry (berries and/or leaves), and macerated bitter melon (fruit and/or leaves and/or seed) in warm (greater than room temperature) water;
- (b) recovering a first extract eluate from the respective extraction of each herbal component;
- (c) repeating step (a), recovering a second extract eluate for each respective herbal component, and pooling the first and second extract eluates of the respective herbal component;
- (d) separately extract a second batch of each of macerated hawthorn, macerated green tea leaves, macerated Gynostemma pentaphyllum leaves, macerated mulberry, and macerated bitter melon in an aqueous alcohol (e.g., 70% ethanol);
- (e) recovering a first aqueous alcohol extract eluate from the

respective aqueous alcohol extraction of each herbal component; (f) repeating step (d), recovering a second aqueous alcohol extract eluate from the respective aqueous alcohol extraction of each herbal component, and pooling the second aqueous alcohol extract eluate with the respective first aqueous alcohol extract eluate from each herbal component;

(g) recovering the organic residue of each herbal component by reducing the liquid portion of each of the respective pooled eluates by drying (air drying, freeze drying or a combination thereof), in forming a green tea extract powder, a Gynostemma pentaphyllum extract powder, a hawthorn extract powder, a mulberry extract powder, and a bitter melon powder;

(h) combining the green tea extract powder, the Gynostemma pentaphyllum extract powder, the hawthorn extract powder, the mulberry extract powder, and the bitter melon powder in the desired proportions. It is noted that the pooled water extract eluate and the pooled aqueous alcohol extract eluate from each herbal component were dried separately and then the organic residues for that herbal component combined to form the extract powder for that herbal component; or alternatively, the pooled water extract eluate and the pooled aqueous alcohol extract eluate from each herbal component may be combined and then dried to form the extract powder for that herbal component. In yet another alternative, any of one or more of the components may be made singly, or in combination with one or more of the other components, before combining with the remaining components in the desired proportions in forming the herbal extract-based composition.

Detailed Description of the Invention

Definitions

In describing embodiments of the present invention, such terms as "first", "second", "third", "fourth" and the like are words of convenience in order to distinguish between different elements. Such terms are not intended to be limiting as to the sequence of a method

or priority in which the different elements may be utilized.

The present invention relates to a novel herbal extract-based composition that comprises a combination of extracts of Gynostemma pentaphyllum, green tea, hawthorn, mulberry, and bitter melon. The herbal extract composition comprises from about 5 percent to about 20 percent by weight of Gynostemma pentaphyllum extract, about 20 percent to about 40 percent by weight of green tea extract, about 20 percent to about 40 percent by weight of hawthorn extract, about 10 percent to about 20 percent by weight of mulberry extract, and about 10 percent to about 20 percent by weight of bitter melon extract. In a preferred embodiment, the novel herbal extract-based composition comprises a combination comprising about 10 percent by weight of Gynostemma pentaphyllum extract, about 20 percent by weight of green tea extract, about 30 percent by weight of hawthorn extract, about 20 percent by weight of mulberry extract, and about 20 percent by weight of bitter melon extract.

The herbal extract-based composition of the present invention is an arrangement and unique combination that has been found to provide previously unknown or unexpected therapeutic or health-promoting benefits, particularly when the herbal extract-based composition is taken by an individual as a dietary supplement. Depending on the desired use of the herbal extract-based composition according to the present invention to provide one or more particular health-promoting and/or therapeutic effects, the composition can be provided as a main component in a form including, but not limited to, a tea, a liquid extract, a beverage, a gum, a lozenge, and a tablet (including capsule, caplet, or other pill type form). In one embodiment, the herbal extract-based composition is included in a chewing gum formulation. The composition of chewing gum is conventional, and well known to those skilled in the art. For example, a gum base that may be mixed with the composition includes a base comprised of arabic, guar, natural rubber gums; sweeteners

(sugar, stevia, saccharin, sorbitol, aspartame); flavoring agents (e.g., mints, fruits), coloring agents; or a combination thereof. In another embodiment, the composition is used as a tea.

In another embodiment, the herbal extract-based composition is included in a beverage formulation. The composition of beverages are conventional, and well known to those skilled in the art. For example, an aqueous carrier that may be mixed with the composition includes carriers comprised of spring water, filtered water, distilled water, carbonated water, flavored water, "sports" drinks (drinks containing carbohydrates and salts, as known in the art) juices, or combinations thereof. Additionally, the beverage may further comprise components known to the beverage industry including preservative agents, sweeteners, flavoring agents, coloring agents, and combinations thereof.

In another embodiment, the herbal extract-based composition is in extract form. The composition of herbal extracts are conventional, and well known to those skilled in the art. For example, an aqueous carrier that may be mixed with the composition includes carriers comprised of spring water, filtered water, or distilled water. Additionally, the extract may further comprise components including preservative agents, sweeteners, flavoring agents, coloring agents, and combinations thereof.

In another embodiment, the herbal extract-based composition may be incorporated into a tablet (including capsule, caplet, pill, and the like). Suitable bases are known to those skilled in the art to include fillers, binders, coatings, excipients and combinations thereof. For example, base ingredients may include, but are not limited to, plant cellulose, natural silica, magnesium stearate, wax, vegetable glycerides, vegetable stearate, and a combination thereof.

In another embodiment, where topical application to the skin or mucous membranes is desired to provide health-promoting effects, the herbal extract-based composition may be incorporated into a cream or ointment base. Suitable bases are known to those skilled

in the art to include one or more of purified water, lanolin, propylene glycol, mineral oil, tea oil, vegetable or flower oils, glycerin, glycetyl stearate, cetyl alcohol, propylparaben, preservatives, fragrance, and the like. Formulations containing the herbal extract-based composition according to the present invention may comprise topical agents including, but not limited, to a rinse, a cream, an ointment, a gel, and a suppository. It will be appreciated by those skilled in the art that the amount of the herbal extract-based composition in the formulation will depend on other ingredients in the formulation, the mode of administration of the formulation, the physiologic site to be treated, and the desired health-promoting or therapeutic effect to be provided.

The therapeutic and/or health-promoting benefits provided by the arrangement and unique combination of Gynostemma pentaphyllum extract, green tea extract, hawthorn extract, mulberry extract, and bitter melon extract comprising the herbal extract-based composition of the present invention may be more apparent by the following examples which are provided for purposes of illustration, and not limitation.

EXAMPLE 1

Recent estimates indicate that during the last decade, the incidence of type II diabetes has increased in Americans by about 40%. Additionally, the incidence of the disease in adults in their 30s has increased by 70%. Major predisposing factors to developing type II diabetes include being overweight (current estimates indicate that 61% of Americans are overweight), insulin resistance, and diets high in refined carbohydrates. In diabetic individuals, increased blood concentration of glucose (hyperglycemia) is known to induce pathological complications, including heart disease (particularly as a result of constricting of blood vessels, and atherosclerosis), kidney disease (nephropathy), and eye and nerve complications (neuropathy). Recent studies indicate that strict glucose control can have long term

benefits by helping diabetic individuals avoid the complications of diabetes. A combination of diet, exercise, and dietary supplements has been promoted as a means by which diabetics can control their blood sugar levels and manage their disease.

The herbal extract-based composition of the present invention contains a unique combination of components have health-promoting effects for individuals with diabetes. For example, the herbal extract-based composition may possess hypoglycemic activity that tends to selectively lower blood glucose levels which are elevated (hyperglycemic), but not significantly modify normal blood glucose levels (e.g., normal blood glucose generally ranges from about 70 to about 120 milligrams of glucose per deciliter of blood). Additionally, the herbal extract-based composition possesses a plurality of antioxidants such as saponins, flavonoids, and anthocyanins (including proanthocyanidins). These antioxidants enhance the function of the liver, an organ that works with the pancreas to regulate glucose levels in an individual. Additionally, the antioxidants and other beneficial ingredients of the herbal extract-based help to prevent complications of diabetes. For example, these ingredients can dilate blood vessels, reduce atherosclerosis, promote the health of endothelium, and increase coronary blood flow in inhibiting the blood vessel constriction and heart complications induced by hyperglycemia.

Also, the herbal extract-based composition may be used as a dietary supplement in other conditions characterized by hyperglycemia. For example, it is now well established that most patients who have just completed major surgery have elevated blood glucose concentrations. It is believed that the hyperglycemia contributes to surgical complications such as an increased risk of infections. For example, in a study of surgical patients who stayed 6 days or longer in Intensive Care Units, deaths occurred at twice the rate when patients' blood sugar concentrations were twice normal values, as compared to the death rates of patients whose blood sugar concentra-

tions were kept near normal concentrations. Thus, a dietary supplement that can help to control blood glucose levels in patients recovering from surgery may be desirable.

To illustrate the enhanced (e.g., unexpected efficiency of the) hypoglycemic activity of the herbal extract-based composition of the present invention, the herbal extract-based composition was in powder form. Individuals having hyperglycemia took a half a teaspoon of the powder as a daily, dietary supplement in conjunction with a consistent diet (no significant dietary changes during the evaluation period). The average blood glucose levels were about 140 mg/dl in the individuals before taking the herbal extract-based composition. After 2 days of taking the herbal extract-based composition, the average blood glucose levels were normalized to 110 mg/dl, and continued to remain normalized during the evaluation period.

EXAMPLE 2

In this embodiment, illustrated in animals is the use the herbal extract-based composition according to the present invention to efficaciously lower blood glucose levels, as well as to effect other health-promoting responses, in treatment of diabetes. In this example, a standard animal model for diabetes was used, alloxan-induced diabetic rats. The herbal extract-based composition was administered to rats orally as a liquid via a gastric tube. As a control for the test, other rats received water via a gastric tube. The herbal extract-based composition or the water was each administered to three different groups of rats. Group A received the herbal extract-based composition (6 rats) or the water (6 rats), and had blood glucose assessed before receiving alloxan. Group B received the herbal extract-based composition (6 rats) or the water (6 rats) seven days after receiving alloxan, and then blood glucose was assessed. Group C received the alloxan first, and then received either the herbal extract-based composition (6 rats) or the water (6 rats) 4 days later, and then blood glucose was assessed. Alloxan was

administered intravenously at a single dose of 30 mg/kg.

The results of treatment, as measured by average fasting blood glucose levels (expressed in mg/dl \pm standard deviation), are illustrated in Table 1.

Table 1

Liquid received	Group A	Group B	Group C
water	81.5 \pm 7.5	190.3 \pm 15.3	287.5 \pm 20.6
herbal extract-based composition	78.9 \pm 7.3	181.3 \pm 16.5	140.0 \pm 12.7

It is apparent from these results, that the herbal extract-based composition according to the present invention can significantly reduce hyperglycemia in diabetes as demonstrated with alloxan-induced diabetic rats. It was also observed that on average there was a 10 percent decrease in the weight of alloxan-induced diabetic rats. However, treatment of alloxan-induced diabetic rats with the herbal extract-based composition according to the present invention resulted in little or no decrease in the overall weight of the treated rats. Toxicology studies of rats which received the herbal extract-based composition according to the present invention (e.g., via gastric tube at about 400 mg daily) for 45 days showed no gross histopathological changes in the central nervous system, heart, lungs, kidneys, liver or spleen.

EXAMPLE 3

In this embodiment is illustrated a process for preparing the herbal based-extract of the present invention. In this process of preparation, selectively extracted from each component herb are compounds (some yet to be chemically defined) with particular types of pharmacological and/or health promoting activities. Using this process results in extracts that contain high concentrations of these compounds that comprise active ingredients in the herbal extract-based

composition of the present invention. The extraction process of the present invention selectively extracts target compounds of desired pharmacological and/or health promoting activity, and thus, the extraction process should not be considered a "traditional extraction"; and the resultant extract is more appropriately viewed as a selective concentration of a combination of active components rather than a "total extract". Thus, using the method according to the present invention is an approach to control the quality of, and standardize the composition of the target compounds to be selectively extracted for, the herbal extract-based composition of the present invention.

The method according to the present invention comprises: separately extracting each of hawthorn (berries and/or leaves, green tea (leaves), Gynostemma pentaphyllum (leaves), mulberry (berries and/or leaves), and bitter melon (leaves and/or seed and/or fruit); drying extraction eluates obtained from the extracting of each of hawthorn, green tea, Gynostemma pentaphyllum, mulberry, and bitter melon to obtain organic residues in forming a hawthorn extract powder, green tea extract powder, a Gynostemma pentaphyllum extract powder, a mulberry extract powder, and a bitter melon powder; and combining the green tea extract powder, the Gynostemma pentaphyllum extract powder, the hawthorn extract powder, the mulberry extract powder, and the bitter melon powder in desired proportions to form the herbal extract-based composition. In one embodiment of the present invention, the method comprises the steps of:

- (a) separately extracting a first batch of macerated hawthorn, macerated green tea, macerated Gynostemma pentaphyllum, macerated mulberry, and macerated bitter melon (each referred to as a "herbal component") in warm (greater than room temperature) water;
- (b) recovering a first extraction eluate from the respective extraction of each herbal component;
- (c) re-extracting each herbal component by repeating step (a), recovering a second extraction eluate, and pooling the second

extraction eluate with the first extraction eluate of the respective herbal component;

(d) separately extracting a second batch of macerated hawthorn, macerated green tea, macerated Gynostemma pentaphyllum, macerated mulberry, and macerated bitter melon in an aqueous alcohol (e.g., 70% ethanol), and recovering alcohol extraction eluates for each herbal component;

(e) recovering the organic residue from each of the extraction eluates by reducing the liquid portion of each of the extraction eluates by drying (air drying, freeze drying, or a combination thereof) in forming a green tea extract powder, a Gynostemma pentaphyllum extract powder, a hawthorn extract powder, and a mulberry extract powder and a bitter melon extract powder;

(h) combining the green tea extract powder, the Gynostemma pentaphyllum extract powder, the hawthorn extract powder, the mulberry extract powder, and the bitter melon powders in the desired proportions to produce the herbal extract-based composition according to the present invention.

In one embodiment, the extraction eluate produced for a herbal component using a water extraction may first be combined with the extraction eluate produced for the same herbal component using aqueous alcohol before the organic residue is recovered for that herbal component (per step (e)).

In a preferred embodiment, the process for making the herbal extract-based composition comprises the steps of:

(a) macerating hawthorn berries, macerating mulberry leaves, macerating bitter melon seeds and/or fruit, macerating green tea leaves and macerating Gynostemma pentaphyllum leaves into small pieces (e.g., millimeter size) while keeping each herbal component separate;

(b) placing the macerated hawthorn, macerated mulberry, macerated bitter melon, macerated green tea, and macerated Gynostemma pentaphyllum into separate containers;

(c) separately diluting each herbal component from step (b) in warm

water, preferably at in a temperature range of between approximately 70°C to 80°C, preferably in a ratio range of water to each herbal component of five to one;

(d) allowing each herbal component to soak in the warm water for at least 1 hour (preferably for 2-4 hours);

(e) collecting an extraction eluate from each soaking of the herbal components into separate receptacles;

(f) re-extracting the macerated hawthorn, macerated green tea, macerated bitter melon, macerated Gynostemma pentaphyllum, and macerated mulberry in a warm solution of water by repeating steps (c) - (d);

(g) collecting a re-extraction eluate from each re-extraction of each of the herbal components and pooling the re-extraction eluate with the extraction eluate of the respective herbal component; and in an extraction of a second batch of macerated hawthorn, macerated green tea, macerated Gynostemma pentaphyllum, macerated bitter melon, and macerated mulberry in an aqueous alcohol (e.g., 50% to 70% alcohol solution);

(h) placing the second batch of macerated hawthorn, macerated green tea, macerated Gynostemma pentaphyllum, macerated bitter melon, and macerated mulberry into separate containers;

(i) separately diluting each herbal component from step (h) in an aqueous alcohol solution (preferably, 70% ethanol; preferably at room temperature, e.g., a range of between approximately 25°C to 40°C; preferably in a ratio range of alcohol solution to each herbal component of five to one);

(j) allowing each herbal component to soak in the aqueous alcohol solution for at least 1 hour (preferably for 2-4 hours);

(k) collecting the aqueous alcohol solution extraction eluate from the soaking of each of the herbal components into separate receptacles;

(l) re-extracting the second batch of macerated hawthorn, macerated green tea, macerated bitter melon, macerated Gynostemma pentaphyllum, and macerated mulberry in an aqueous alcohol solution by repeating

steps (i)-(j);

- (m) collecting the aqueous alcohol solution re-extraction eluates from the soaking of each of the herbal components and pooling each aqueous alcohol solution supernatant re-extract with the aqueous alcohol solution extraction eluate of the respective herbal component;
- (n) recovering the organic residue from the pooled aqueous alcohol extraction eluate of each herbal component by reducing the liquid portion of each of the respective pooled aqueous alcohol extraction eluate by drying (air drying, freeze drying, or a combination thereof) in forming a green tea extract powder, a Gynostemma pentaphyllum extract powder, a hawthorn extract powder, a mulberry extract powder, and a bitter melon extract powder; and
- (o) combining the green tea extract powder, the Gynostemma pentaphyllum extract powder, the hawthorn extract powder, the mulberry extract powder, and the bitter melon extract powder in the desired proportions to form a herbal extract-based composition.

In illustrating a preferred embodiment, and following the process for producing the herbal extract-based composition, the herbal extract-based composition may be formed by mixing about 5 percent to about 15 percent by weight of Gynostemma pentaphyllum extract powder, with about 15 percent to about twenty five percent by weight of green tea extract powder, with about 20 percent to about 30 percent by weight of hawthorn extract powder, with about 15 percent to about 20 percent by weight of mulberry extract powder, and with about 15 percent to about 20 percent by weight of bitter melon extract powder. Continuing this illustration of a preferred embodiment, the herbal extract-based composition is formed into a tablet, wherein the combined weight of the extract powders comprises a weight in the range of about 250 mg to about 500mg. In a preferred embodiment, such tablet form, and intrinsic to the herbal extract-based composition is typically found at least about 15% by weight of proanthocyanidins, at least about 10% by weight saponins, at least 15% by weight

polyphenols, at least 10% by weight of mulberry flavanoids, and at least 10% by weight of bitter melon components which have anti-diabetic effects (e.g., reduce hyperglycemia). In such tablet form, a preferred dosage and regimen as a dietary supplement for an adult male or female to effect the health-promoting and/or therapeutic effects provided by the herbal extract-based composition of the present invention is 1 tablet, two to three times daily; and preferably shortly before meals.

From the foregoing, it will be obvious to those skilled in the art that various modifications in the above-described methods, and compositions can be made without departing from the spirit and scope of the invention. Accordingly, the invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. Present embodiments and examples, therefore, are to be considered in all respects as illustrative and not restrictive, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. An herbal extract-based composition comprising: a combination of a water extract and aqueous alcohol extract of Gynostemma pentaphyllum, a combination of a water extract and aqueous alcohol extract of Crataegus pinnatifidia (hawthorn), a combination of a water extract and aqueous alcohol extract of Camellia sinensis (green tea), a combination of a water extract and aqueous alcohol extract of mulberry, and a combination of a water extract and aqueous alcohol extract of Momordica charantia (bitter melon).

Abstract

Provided is an herbal extract-based composition comprising an extract of Gynostemma pentaphyllum, an extract of Crataegus pinnatifidia (hawthorn), an extract of Camellia sinensis (green tea), an extract of mulberry, and an extract of Momordica charantia (bitter melon). Also provided is a process for preparing a herbal extract-based composition which comprises separately extracting each of hawthorn, green tea, Gynostemma pentaphyllum, mulberry, and bitter melon; drying extraction eluates obtained from the extracting of each of the herbal components to obtain organic residues in forming a hawthorn extract powder, green tea extract powder, a Gynostemma pentaphyllum extract powder, a mulberry extract powder, and a bitter melon powder; and combining the green tea extract powder, the Gynostemma pentaphyllum extract powder, the hawthorn extract powder, the mulberry extract powder, and the bitter melon powder in desired proportions to form the herbal extract-based composition which has health-promoting effects including potent inhibition of free radicals, and including hypoglycemic activity.